CONTRACT RESEARCH REPORT
December 2025

EXPLORING ON-BODY INJECTORS

Novel devices: optimising drug delivery in multiple myeloma

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Please cite this report as:
Fong H., Cubi-Molla P., Garau M., 2025. Novel devices: optimising drug delivery in multiple myeloma. OHE Contract Research Report, London: Office of Health Economics. Available at: https://www.ohe.org/publications/novel-devices-optimising-drug-delivery-in-multiple-myeloma

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Funding and Acknowledgements

This Contract Research Report was commissioned and funded by Sanofi.

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List of abbreviations

EMA	European Medicines Agency
HCP	Healthcare professional
HTA	Health technology assessment
IV	Intravenous
KRQ	Key research question
mAb	Monoclonal antibody
MM	Multiple myeloma
NICE	National Institute for Health and Care Excellence
OBI	On-body injector
OBDS	On-body delivery system
SOC	Standard of care
SC	Subcutaneous
SCT	Stem cell transplant
QALY	Quality-adjusted life year

Executive Summary

Biological medicines (biologics) have transformed the treatment landscape of multiple myeloma and cancer as a whole. The notable shift from cytotoxic agents to targeted therapies has enabled subcutaneous (SC) administration as a practical alternative to intravenous (IV) infusion. There is also growing emphasis on improving patient experience, optimising healthcare workflows, and realising the full clinical and economic value of medicines—trends that favour more convenient and flexible delivery methods. This is particularly relevant in multiple myeloma where patients often undergo extended treatment courses and biologics provide substantial improvements in survival outcomes.

SC delivery offers advantages over IV infusion, including reduced treatment burden, greater time and location flexibility, and potential efficiency gains. However, current SC administration in cancer care is still predominantly performed manually via syringe injection. Physiological constraints of SC delivery and the complexity of biologics limit injection volumes, often requiring large-gauge needles and resource-intensive preparation processes. These factors add to the existing treatment burden for patients and workload for healthcare professionals (HCPs). Research into SC formulations highlights not only pharmacological advances in biologics but also the persistent operational challenges of preparation, administration, and integration into clinical pathways.

Novel administration devices, most notably on-body injectors (OBIs), offer an emerging solution. These devices adhere to the patient's skin to deliver pre-programmed doses subcutaneously over a set period, eliminating the need for manual injections. OBIs provide distinct advantages to the patient over conventional syringe administration. For example, OBIs accommodate high-volume formulations, enable automated, hands-free delivery, and are designed for ease of use through simple vial transfer and loading mechanisms. They also incorporate features that improve patient comfort and safety, such as smaller and concealed needles with retractable safety mechanisms. Together, these design elements can enhance patient experience, reduce needle-related anxiety, improve treatment adherence, and minimise disruptions to daily activities.

For HCPs, the use of OBIs provides significant benefits by simplifying preparation and administration, reducing care burden and time requirements, and lowering the risk of physical strain and occupational injuries. These improvements contribute to greater job satisfaction, reduced absenteeism, and enhanced clinical efficiency. At the health system level, OBIs offer potential to streamline workflows, expand treatment capacity, and support decentralised models of care—an especially valuable attribute in resource-constrained settings. Such operational efficiencies might contribute to both healthcare sustainability and cost-effectiveness, in addition to those provided by SC syringes.

With SC biologic formulations expected to grow, adopting OBIs in cancer care represents a strategic opportunity to build on existing benefits of SC drug delivery, and further advance efficiency, sustainability, and patient-centred service delivery across oncology.

Key points

- Novel administration devices, once considered supplementary in biologic-device combinations, may gain strategic importance as subcutaneous biologic injections become integral to multiple myeloma treatment.
- Wider adoption of On-Body Injectors can help overcome formulation and delivery challenges, unlocking the full value of biologics and other anti-cancer medicines.

1 Introduction

1.1 Biologics: driving innovation in the treatment of multiple myeloma

Biological medicines ('biologics') have fundamentally transformed the treatment landscape of multiple myeloma (MM) and cancer more broadly. Produced using living organisms or derived from biological sources, these therapies represent a paradigm shift from traditional chemotherapy by harnessing and enhancing the body's immune system to target malignant cells with greater precision. This targeted approach enables biologics to provide improved side effect profiles and enhanced treatment tolerability, while effectively halting tumour progression (Papież and Krzyściak, 2021).

The biologics arsenal in MM encompasses several distinct therapeutic categories, each leveraging different biological mechanisms. Monoclonal antibodies (mAbs) constitute one prominent category, with agents targeting the CD38 marker protein demonstrating substantial benefits to survival outcomes and gradually incorporating into standard of care (SOC) protocols (Dimopoulos et al., 2021). MAbs directed at alternative pathways also provide valuable options in relapsed and refractory settings, expanding treatment possibilities for patients.

Beyond mAbs, the biologics landscape includes a diverse range of therapies with distinct mechanisms of action, offering expanded treatment options across disease stages, from newly diagnosed to heavily pretreated, refractory MM.

1.2 The treatment burden amidst therapeutic advances

Despite progress in the space , therapeutic management of MM remains complex. The increasingly common addition of a fourth adjunctive therapy into the standard triple-drug combination regimen[1] in early-line treatment has shown improved survival outcomes (Dimopoulos et al., 2021), but can also exacerbate existing treatment burden.

Treatment burden refers to the combination of healthcare tasks and self-care activities that patients must undertake as part of their medical care, which has an impact on patient functioning and well-being (Lyall et al., 2022).

Patients can become overburdened when the breadth and depth of these tasks exceed their capacity to manage them effectively. Although patients manage and perceive treatment-related workload to varying degrees, those at later disease stages, who typically have received multiple treatment options and episodes, have been shown to experience higher treatment burden (Cheng and Levy, 2019). A critical consequence of elevated treatment burden is its potential to lead to treatment non-adherence (Selvakumar et al., 2023), discontinuation, or even treatment refusal.

With medical advancement and the introduction of novel therapeutic agents, treatment burden associated with new drug formulations and methods of administration can translate to care burden and workforce challenges experienced by healthcare professionals (HCPs). Healthcare systems face capacity constraints, with infusion centres

[1] *Triple-drug combination therapy refers to a regimen comprising an immunomodulatory drug, a protease inhibitor, and a steroid, but does not include biologics.*

operating with unprecedented utilisation and nursing staff managing increasingly complex treatment protocols (Challinor et al., 2020; Dodhia et al., 2023).

This has led to greater consideration of system-level impacts when introducing health technologies in clinical practice, alongside three notable shifts in cancer therapy delivery. The primary shift observed is the transition away from traditional cytotoxic agents towards more targeted therapies. Secondly, targeted biologics, which can achieve efficacy with smaller, more precise doses, have made subcutaneous (SC) administration a viable alternative to intravenous (IV) infusion. Finally, growing emphasis on improving patient experience, enhancing health system workflow efficiency, and leveraging the full therapeutic and socio-economic value of medicines has contributed to a broader shift towards more convenient modes of drug delivery, both within and beyond traditional clinical settings—an evolution that SC delivery technologies are well positioned to support.

1.3 The case for optimising drug delivery

The SC method of delivery has gathered increasing interest due to its potential to reduce treatment and care-related burden on patients, HCPs, and health systems, while accommodating greater time and location flexibility compared to IV infusions. However, despite their recognised benefits, current SC administration, typically by syringes, faces significant challenges that limit the full realisation of its advantages.

The fundamental challenge lies jointly between the nature of biological medicines and the physiological constraints of SC delivery. Unlike traditional therapies consisting of small, synthetic molecules, biologics are large, structurally complex proteins that are physically and chemically less stable (Badkar et al., 2021). This creates inherent formulation and delivery challenges where SC syringe injections are typically limited to volumes of 1-2 mL (Badkar et al., 2021). Current approaches using large-volume formulations with absorption-enhancing enzymes require larger gauge needles, leading to increased injection discomfort, extended injection times, and additional burden on HCPs through lengthy preparation processes (Bittner, Richter and Schmidt, 2018; Desai et al., 2025a; b).

An emerging solution to these delivery challenges lies in novel administration devices, most notably on-body injectors (OBIs), also referred to as on-body delivery systems (OBDSs). These innovative drug delivery devices enable the administration of pre-programmed doses of medication subcutaneously over a specified period by adhering directly to the patient's skin (Badkar et al., 2021), eliminating the need for manual syringe push. OBIs can accommodate large-volume biologic injections while enhancing ease of use through automatic loading, improving safety with smaller, hidden, retractable needles, and significantly simplifying preparation and administration processes. In doing so, they address multiple components of treatment and care-related burden simultaneously. In contrast to other disease areas such as diabetes, the availability of OBIs and other hands-free administration devices in oncology remains limited (Guo et al., 2024).

Novel administration devices such as OBIs have long been viewed as supplementary tools within biologic-device combinations in oncology (Guo et al., 2024). As clinical guidelines in Europe and other regions increasingly recommend biologics as an integral component of MM treatment, the role of these devices is shifting. Extending the use of these innovations may not only overcome formulation and delivery challenges but also unlock the full value of biologics and other anti-cancer drugs as a whole.

1.4 About this report

As biologics with SC formulations assume an increasingly prominent role in MM treatment, novel administration devices such as OBIs are expected to enter the market as integral components of drug-device combinations that facilitate SC delivery. This research explores the possible benefits of OBIs use in existing cancer care and examines how they may address existing unmet needs in MM treatment administration across the following countries: France, Germany, Italy, Spain, and the UK.

2 Methodology

2.1 Research questions

The primary objective of this report is to demonstrate the potential benefits of adopting OBIs for administering MM biologic treatments in clinical settings. Three key research questions (KRQs) guide this analysis:

- **KRQ1.** What are the current unmet needs and challenges around drug delivery in MM?
- **KRQ2**. How can OBI adoption improve patient outcomes and experience beyond traditional clinical endpoints?
- **KRQ3**. How can OBI implementation alleviate health system challenges and workforce pressures while enhancing care efficiency?

These research questions are addressed sequentially in the main report sections (Sections 3, 4, and 5, respectively).

2.2 Scope

This report explores how adopting OBIs can address existing unmet needs in MM treatment administration across five European countries: France, Germany, Italy, Spain, and the UK.

Although manufacturers are increasingly investigating and launching OBIs, only few non-insulin OBI devices are currently available, particularly in oncology (Guo et al., 2024). At present, only one OBI is commercially available in supportive cancer care, indicated to reduce infection risk due to low white blood cells in patients receiving chemotherapy (Amgen, 2018).

Given the absence of OBIs specifically approved for MM treatment delivery, we utilise this existing OBI in oncology as a reference case for demonstrating the potential impact of OBI adoption in MM management. Our analysis predominantly draws upon published evidence related to this analogue case, supplemented by ongoing investigational trial results for upcoming OBIs expected to enter the oncology treatment landscape. This approach is detailed in Sections 4 and 5, which describe OBI impacts for patients, HCPs, and health systems.

2.3 Targeted literature review

A targeted literature review of peer-reviewed publications was conducted using Embase, Ovid MEDLINE, and Ovid Nursing Database. We applied a PICO (Population, Intervention, Comparator, and Outcome) search framework, incorporating geographic restrictions aligned with our study scope. The search strategy employed a two-part approach corresponding to KRQ 1, and KRQs 2 and 3, respectively, and included studies published from 2015 to present. This timeframe captures relevant literature following the European Medicines Agency (EMA) approval of the reference OBI analogue in 2018 (Amgen, 2018). Detailed search strategies and eligibility criteria are presented in **Appendix A**.

To supplement the information retrieved from peer-reviewed publications, we also did a targeted review of grey literature from nursing journals and targeted searches of clinical practice guidelines for search one (related to KRQ 1) (see **Appendix B**). For the second search (KRQ 2 and 3), additional targeted searches were performed using the PubMed database to identify additional literature related to SC injections.

Detailed identification, screening, and inclusion of articles for full text extraction are presented as a PRISMA flow chart in **Appendix C**.

2.4 Analytical approach

Relevant articles and insights were extracted using a standardised data extraction form. We retrieved the relevant information related to MM SOC; challenges and unmet needs related to existing drug administration; and the impacts associated with OBIs compared to the SOC.

Challenges and unmet needs, as well as the impacts of using OBIs (instead of SOC) were structured across three levels: patients, HCPs, and health systems. A thematic analysis of the included articles was also conducted to identify impact categories within each level.

3 Current landscape of drug delivery in multiple myeloma

3.1 Epidemiology, disease burden, and treatment innovation

MM is a haematological malignancy characterised by the abnormal production of plasma cells in the bone marrow (Raab et al., 2009). Severe complications can include bone lesions, kidney damage, and anaemia, contributing to significant morbidity and mortality. As the second most common haematological cancer among adults (Abduh, 2024), MM incidence exhibits geographical variation with high rates reported in Western Europe (Zhuge et al., 2025). A global disease burden study of MM observed that Western Europe experienced the highest age-standardised incidence rate over the past 30 years and reported lower quality-adjusted life years (QALYs) in 2021, compared to other regions (Zhuge et al., 2025). This reflects the substantial clinical and economic burden imposed on the region under analysis by MM.

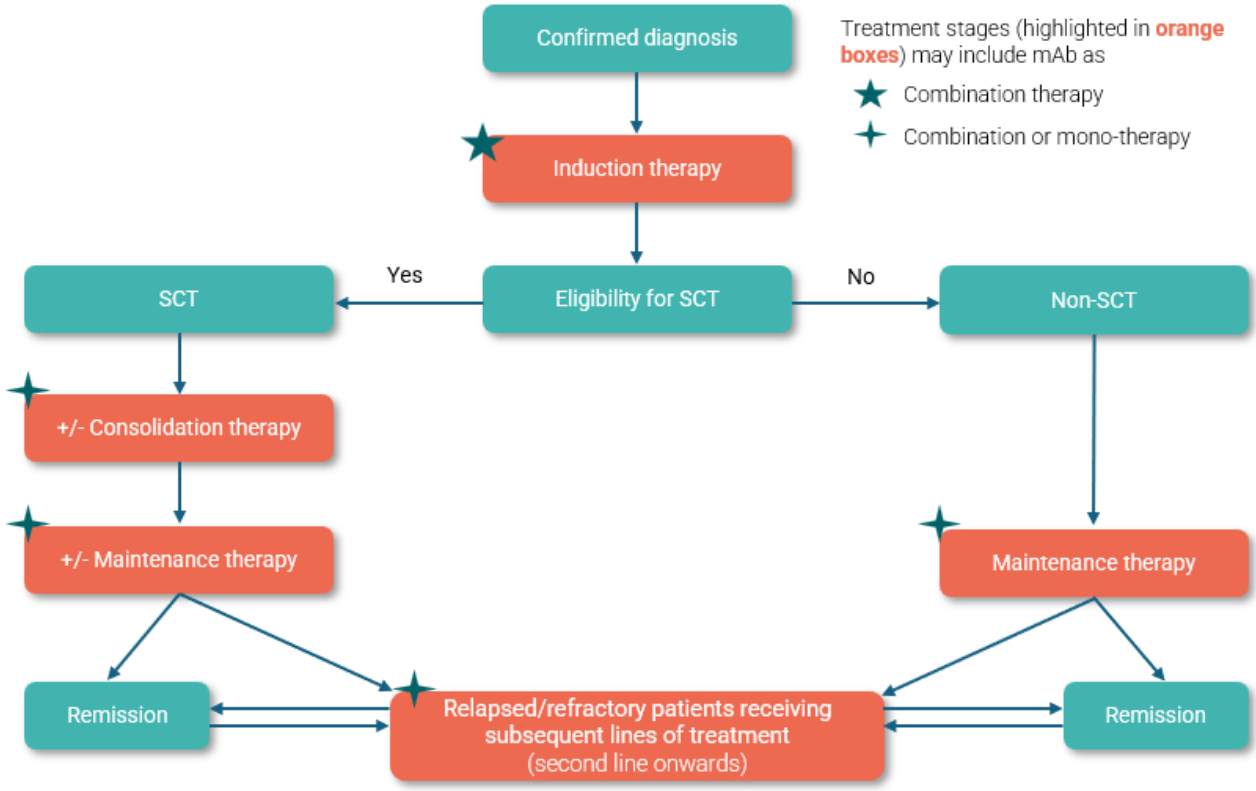
A recent analysis examining MM epidemiology and healthcare resources access revealed two key findings (Ludwig et al., 2020). First, although incidence and mortality were correlated, mortality rates declined even as incidence increased, particularly in Western European countries. Second, survival was significantly associated with access to anti-cancer drugs. Together, these findings suggest that while more cases of MM are being detected, substantial improvement in prognosis, disease progression, and survival has been achieved in Western Europe, largely attributed to access to novel therapeutic agents and biological medicine (Marc S. Raab et al., 2016; Mateos and San Miguel, 2017; Yong et al., 2016) .

Despite these advances, therapeutic management of MM remains complex. Combination therapies provide opportunities to further improve prognosis and survival, and while they are particularly prominent among relapsed and refractory patients receiving later lines of treatment (Marc S. Raab et al., 2016; Yong et al., 2016), they are also increasingly recognised and implemented in early-line treatment.

3.2 Treatment pathway, standard of care, and methods of administration

Although variation in treatment options across countries and institutions is common (particularly as the number of treatment lines increases, see Marc S. Raab et al., 2016; Yong et al., 2016), the general framework describing the treatment pathway in clinical practice guidelines aligns across the five European countries within scope. **Figure 1** outlines the MM treatment pathway, informed by recommendations by the UK's National Institute for Health and Care Excellence (NICE) and European guidance developed jointly by the European Society for Medical Oncology, European Myeloma Network, and European Haematology Association (Dimopoulos et al., 2021, 2025; NICE, 2016).

Figure 1. General treatment pathway for multiple myeloma, adapted from (Dimopoulos et al., 2021, 2025; NICE, 2016; Marc S. Raab et al., 2016).



mAb: monoclonal antibody; **SCT**: stem cell transplant

Different boxes in **Figure 1** denote treatment stages. Upon receiving a confirmed diagnosis, patients receive induction therapy, followed by two distinct treatment pathway alternatives, depending on their eligibility for stem cell transplant (SCT). Regardless of SCT receipt, patients typically receive maintenance therapy, then either achieve remission or progress to a relapsed or refractory state requiring later treatment lines (Marc S. Raab et al., 2016). With combination therapy representing the mainstay treatment in MM, therapies are commonly administered via IV infusion or, increasingly, through SC injections. **Table 1** provides a general comparison of IV infusion and various SC delivery methods.

Compared to IV infusions, SC delivery offers greater flexibility in preparation and administration, including shorter administration times and better mobility during treatment, and is often preferred by patients and HCPs (Magarotto et al., 2024; Zhou et al., 2015). It also improves care efficiency by increasing treatment throughput, reducing patient chair time in infusion centres, and lowering costs related to HCP time and resource use. These advantages are particularly relevant in the evolving treatment landscape of MM, where patients often undergo extended treatment courses, and biologics, especially mAbs, provide substantial improvements in survival outcomes.

Although traditionally incorporated as adjuncts in combination therapy, mAbs are increasingly being used in early-line treatment and integrated into SOC protocols (Dimopoulos et al., 2021). SC delivery is well-suited to support this transition, with the use

of OBIs (also referred to as on-body delivery systems or OBDSs) potentially further enhancing its positive impact by streamlining biologic administration across treatment stages. OBIs are drug delivery devices that attach to the body via adhesion for medicine injection. The delivery mechanism can be either mechanical, typically activated through user button, or electromechanical, enabling (semi-)automatic injection coupled with electronic controls (Badkar et al., 2021). OBIs function as hybrids between SC autoinjectors and syringe pumps (Desai et al., 2023), combining the ease of use of the former with the volume capacity of the latter.

Table 1 Comparison between the characteristics of intravenous infusion and various subcutaneous administration methods in the context of biologics in oncology

ROUTE OF ADMINISTRATION	ADMINISTRATION METHOD	DESCRIPTION	VOLUME CAPACITY	INJECTION CONCENTRATION[2]	ADMINISTRATION TIME IN MINUTE[3]	NEEDLE GAUGE SIZE[4]	INJECTION MECHANISM
Intravenous (IV)	Infusion	Drug vial content is transferred into an IV fluid bag and delivered using an infusion pump.	High, ~100-250mL	Low	30-180	Large, size 20-22	Automatic
Subcutaneous (SC)	Syringe via manual push[1]	Drug vial content is transferred into a syringe and administered manually by injection.	Low, ~1-2mL	High	1-5	Medium, size 23-25	Manual
	Prefilled syringe	Drug content is prefilled by the manufacturer into a syringe, ready for manual injection.	Low-medium, typically ~1-2mL (up to 15mL with enzyme enhancers)	High	1-5	Medium, size 23-26	Manual
	Autoinjector	Drug content is filled by the manufacturer into a hand-held, pen-like device, which delivers the dose automatically using a spring or motor mechanism.	Low, ~2.5mL	High	1-5	Medium, size 23-27	Automatic
	Syringe pumps	The drug vial is inserted directly into a pump system that delivers the medication automatically.	High, up to 30mL	Low	10-20	Medium-small, size 26-29	Automatic
	On-body injector	The drug vial is placed directly into a mobile device attached to the skin, enabling hands-free delivery.	High, up to 100mL	Low	10-15	Small, size 29-30	Automatic

(Table content adapted from Badkar et al., 2021; Desai et al., 2023; Green, Schneider and Lange, 2024; McCloskey et al., 2023).

[1] Manual syringes require manual preparation of vial content by healthcare staff in contrast to prefilled syringes produced by manufacturers. Both manual and prefilled syringes require manual injection. [2] Low injection concentration is desirable due to lower viscosity, shorter injection time, and smaller needles required. An injection concentration equal or above 100mg/mL is considered high (Desai et al., 2023). [3] The presented general injection time (excluding preparation time) may vary across specific biologics and formulations. [4] A higher needle number indicates a smaller needle size.

Biologics are commonly prescribed during induction, maintenance, and later-line therapies (highlighted in orange boxes of **Figure 1**), and OBIs provide a patient-centred, hands-free delivery option during these phases.

3.3 Evolution and practical limitations of current subcutaneous administration for patients, professionals, and systems

Traditionally, most biologic products were formulated at low concentrations for IV infusion to preserve biological stability (Garidel et al., 2017). However, the shift toward mAbs and longer-acting SC therapies has driven the development of high-concentration SC formulations (Desai et al., 2023). This shift introduces delivery challenges, as higher concentration increases solution viscosity, while most existing delivery devices only accommodate small volumes (Desai et al., 2023).

The first commercially available high-volume SC products often rely on manual vial-syringe combinations (Li and Easton, 2018), requiring manual preparation and administration by HCPs. These non-prefilled syringes store drugs either as liquid ready for extraction or powder requiring reconstitution prior to injection (Li and Easton, 2018). While SC prefilled syringes and autoinjectors are more convenient, they are typically restricted to low volumes and still require manual injection (Desai et al., 2023). Alternative delivery options, such as SC syringe pumps, can support controlled or higher-volume injections. However, they are often bulky, complex to set up, and may restrict patient mobility due to prolonged infusion times. Additionally, high-viscosity formulations, especially those co-formulated with absorption-enhancing enzymes, often require larger gauge needles, contributing to increased injection discomfort and extended administration durations (Desai et al., 2025b). These factors add to the treatment burden for patients and increase preparation and administration demands for HCPs.

Given that manual injections remain the predominant mode of SC administration in clinical settings, there is a clear need to introduce innovative alternatives in SC delivery to alleviate existing healthcare pressures and delivery additional value for patients and health systems.

3.4 How on-body injectors can address unmet needs

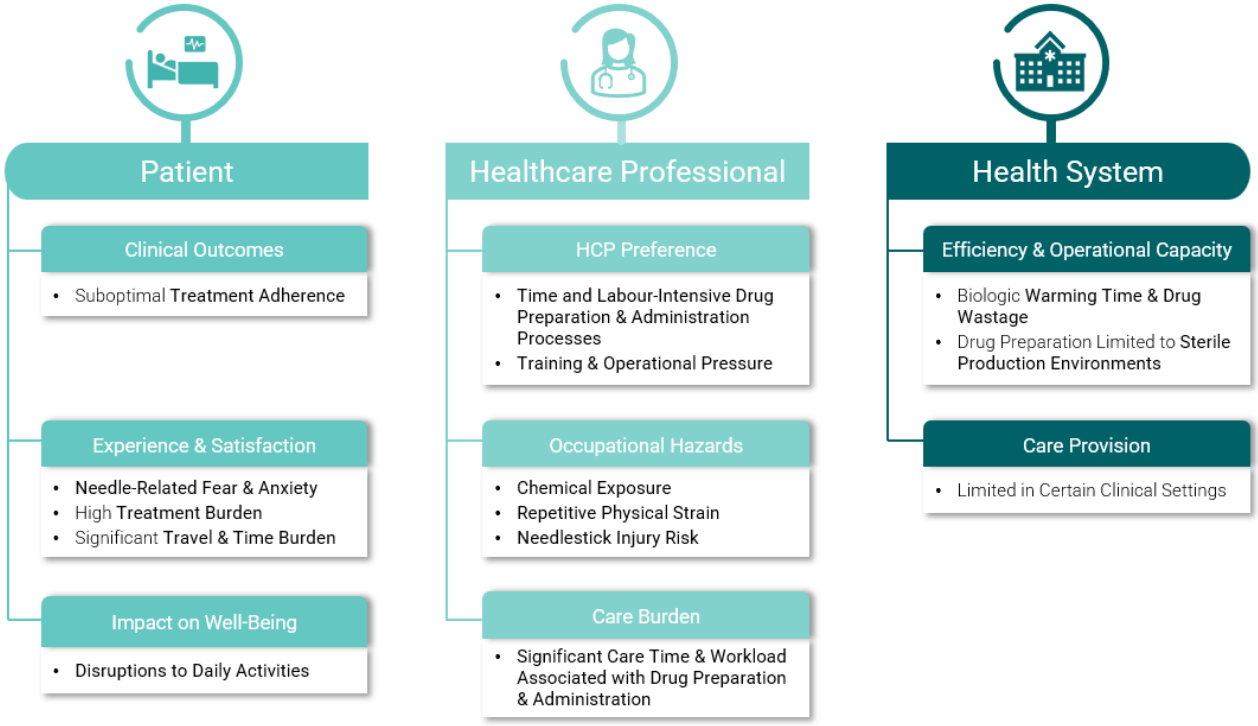
Following information extraction from the literature review, a thematic analysis of the included articles was conducted. As previously described (Section 2.4), we retrieved the relevant information related to MM SOC (now identified as SC syringe injections, see Section 3.3); challenges and unmet needs related to existing drug administration; and the impacts associated with OBIs compared to SC syringe injections.

The findings related to 'challenges and unmet needs', as well as 'impact of using OBIs (instead of SC syringe injections)' were structured across three levels: patients, HCPs, and health systems. The thematic analysis performed identified three, three, and two impact categories related to MM patients, healthcare, and health system, respectively (see Figure

2). Note that, while these categories are not explicitly used in the following sections, they inform the analytical presentation and writing.

Figure 2 summarises the unmet needs and challenges related to SC manual syringe delivery, by category. These include significant treatment burden and logistical challenges for patients, labour-intensive and technically demanding processes with safety risks for HCPs, and workflow delays, drug wastage, and capacity constraints at the health system level. Using the framework illustrated in **Figure 2**, the following sections extend the information about the challenges and map how OBIs could potentially address them.

Figure 2 Framework outlining challenges and unmet needs related to standard subcutaneous manual injection delivery.



4 Improving patient-centred care with on-body injectors

4.1 Comparable effectiveness and safety to manual subcutaneous syringes

A critical aspect of OBI implementation is its ability to maintain therapeutic equivalence with conventional SC delivery methods. Clinical studies of anti-cancer biologics and supportive cancer therapies have demonstrated that OBIs deliver bioequivalent drug exposure compared to manual syringes (Tang et al., 2024; Wynne et al., 2025). In a real-world study with matched cohorts, medicines administered using OBIs and prefilled syringes demonstrated comparative effectiveness with the incidence of chemotherapy-associated adverse events being lower in the OBI group (McBride et al., 2021).

A trial investigating the safety of OBIs also reported minimal skin reddening and no pain regarding device adhesion, needle insertion, and device removal (Tang et al., 2024). The incidence of immunogenicity and treatment-emergent antidrug antibodies remained similar compared to syringe injections. With adverse event rates being comparable across groups, total healthcare resource utilisation and costs for hospitalisations, emergency department visits, and pharmacy claims showed no significant differences between OBI and syringe delivery.

These combined outcomes position OBI as a clinically sound advancement in patient care delivery with maintained therapeutic effectiveness. However, for chronic conditions like MM, where patients face multiple treatment episodes with some requiring lifetime therapy and increasing treatment burden, elements beyond clinical outcomes demonstrate additional reasons why OBIs can enhance patient experience and support patient-centred care.

4.2 Looking beyond clinical outcomes: patient preference for novel drug delivery

Patient preferences have become a critical component of cancer care and shared decision-making, particularly for scenarios where patients typically receive multiple treatment combinations over extended period, such as MM (Fifer et al., 2020). Patient-clinician alignment in treatment preferences can lead to improved treatment adherence and outcomes (Umar et al., 2012). However, HCPs are often unaware of individual patient preferences, potentially underestimating the impact of treatment attributes on patients' quality of life (Ailawadhi et al., 2025). Patients have expressed appreciation for HCPs who recommend treatment options that account for patient treatment goals and preferences (Ailawadhi et al., 2025).

While SC administration already reduces discomfort compared with IV delivery, OBIs can further enhance patient comfort by enabling convenient hands-free administration with smaller needles. In a randomised crossover trial comparing OBIs and prefilled syringes across treatment cycles, a clear preference emerged for OBIs across all administration settings, including oncology practices, mixed locations, and home environments (Metz et al., 2021). Notably, patients on longer treatment journeys were more likely to value flexible administration modes and frequency (Fifer, Galinsky and Richard, 2020), suggesting that OBIs may be particularly relevant in later treatment stages. Interestingly, this preference

was also observed in early-stage cancer patients, indicating that treatment convenience is valued across disease settings.

The primary drivers of OBI preference were reduced time burden, fewer disruptions to daily and social activities, and greater flexibility in daily planning—benefits especially valued by patients living further away from oncology centres. Patient preference for manual SC syringes declined as travel distance increased, reflecting the growing importance of convenience over time (Metz et al., 2021). These patterns were predominantly observed in settings where both OBIs and syringes were administered in outpatient care. This pattern was also confirmed in a patient preference study assessing treatment priorities and novel therapies across Europe, Japan, and the US, where managing logistic burden proved critically important for patients. Younger patients particularly prioritised treatment convenience, considering both route and time of administration, while European patients prioritised treatments requiring limited treatment time commitment (Ailawadhi et al., 2025), both of which may be supported by OBIs.

An international online survey of over 2,000 patients further highlighted the potential of OBIs to improve adherence among cancer patients with needle phobia (Alsbrooks and Hoerauf, 2022). High-volume SC injections often require larger needle gauges which can heighten discomfort and contribute to needle-related anxiety. This, in turn, may lead to treatment refusal or result in missed or delayed appointments. The survey found that more than 60% of patients report moderate to severe needle fear, with nearly 90% expressing preference for devices with hidden or invisible needles—a feature commonly integrated in OBIs, which also tend to use thinner and shorter needles than SC syringes via manual push (Alsbrooks and Hoerauf, 2022; Desai et al., 2025b).

Although some patients may initially express reservations about using this category of device, these concerns were shown to decline with experience, and patients become more likely to choose OBI over syringe delivery once they gained familiarity (Metz et al., 2021). This experience-driven shift in preference suggests that OBIs offer a patient-centric solution that not only addresses lifestyle needs, but also enhances treatment experience, ultimately improving patient satisfaction and supporting sustained engagement. It also underscores the importance of clinician consultation and shared decision-making when prescribing novel administration devices.

4.3 Patient implications on treatment receipt and access

Treatment adherence is a key determinant of real-world effectiveness and long-term health outcomes. In many cancers, adherence remains suboptimal due to factors such as age, polypharmacy, and high comorbidity burden-- all highly relevant in MM, where the median age at diagnosis is 70 years and complications are common (Mateos and San Miguel, 2017). A meta-analysis found that in chronic conditions, including cancer, good treatment adherence was associated with a 21% reduction in long-term mortality compared to non-adherence (Walsh et al., 2019).

OBIs may help address known barriers to adherence by simplifying treatment access and administration processes. A multi-centre prospective study found that adherence was higher among patients receiving supportive cancer therapy via OBIs than with prefilled syringes, indicating that OBIs may support alignment with clinical guidelines and sustained engagement with the therapy (Rifkin et al., 2022).

As previously mentioned, time burden is a significant factor that influences treatment access and continuation. Many patients report that the time spent travelling to and waiting at treatment centres interferes with their daily lives and well-being. For example, over one-third of MM patients on maintenance reported time burden as a barrier to care (Banerjee et al., 2024). This burden can be individual-specific, disease status-specific

(relating to whether patients are currently receiving active treatment or in remission), or treatment logistic-related (Di et al., 2024). As such, patient perception of time burden can directly affect their choice of treatment and even lead to refusal or discontinuation (Cytryn et al., 2023; Mian et al., 2023). In later lines of MM treatment, where disease progression and poor health status are more common, the likelihood of treatment discontinuation increases (Yong et al., 2016). Treatment refusal, though rare, has been reported in real-world European data, with patients citing reasons such as emotional exhaustion, hospitalisation requirements, and reluctance to pursue further treatment after multiple relapses (Ailawadhi et al., 2025).

OBIs may even help mitigate these risks as healthcare systems decide to shift treatment delivery from hospital-based settings to community or even home care in the future (see, for example, UK Gov, 2025), thereby reducing the logistical burden of care. This may be especially valuable for patients who feel overwhelmed by complex treatment schedules or who face barriers to frequent travel. By enabling more flexible, less disruptive administration, OBIs have the potential to reduce both intentional and unintentional treatment delays, improve adherence, and lower the risk of treatment refusal, particularly in later treatment stages or among patients with poor functional status (although the impact in the latter might be less pronounced). Aside from the positive impacts on patient treatment burden and treatment adherence, these impacts also address existing burden experienced by HCPs and other health system challenges (explored in Section 5).

Box 1 summarises the unmet needs associated with the SOC and how OBIs provide targeted solutions at the patient level.

Summary Box 1 Mapping how on-body injectors address unmet needs at the patient level.

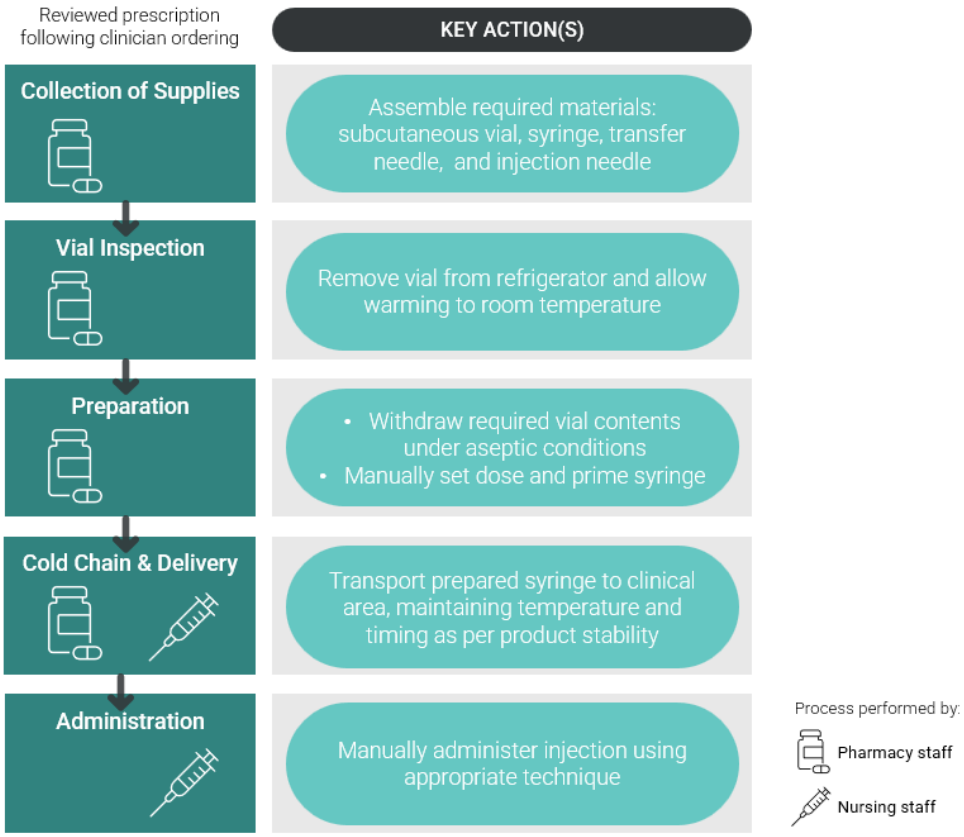
CHALLENGES AND UNMET NEEDS OF STANDARD SC SYRINGES	HOW OBIS CAN ADDRESS CHALLENGES	REFERENCE
High treatment burden from multiple treatment episodes over a patient's lifetime	Align with patient preferences across different treatment stages and care settings	(Fifer et al., 2020)
Disruptions to daily activities and social life due to treatment schedules	Offer flexibility and convenience in administration, and can help reduce disruptions compared with clinic-based SC manual syringe delivery, when used in community or home settings	(Fifer et al., 2020; Metz et al., 2021)
Significant logistical burden in attending treatment appointments	Enable mobility during drug delivery and support potential for decentralised care delivery, lessening burden of frequent care visits	(Ailawadhi et al., 2025; Alsbrooks and Hoerauf, 2022; Banerjee et al., 2024; Metz et al., 2021)
Needle-related fear and anxiety, especially with large-gauge needles	Incorporate hidden or invisible needles	(Alsbrooks and Hoerauf, 2022; Desai et al., 2025b)
Suboptimal treatment adherence, particularly over long treatment durations	Improve adherence and promote sustained patient engagement with treatment	(Rifkin et al., 2022; Walsh et al., 2019)

5 Alleviating health system challenges and pressures with on-body injectors

5.1 The role of healthcare professionals in cancer treatment administration

HCPs, particularly pharmacy and nursing staff, play a crucial role in the preparation and administration of injectable cancer treatments (Desai et al., 2025b; a), ensuring accurate dose delivery and patient safety. To illustrate the operational challenges faced by HCPs and healthcare systems, we first outline the step-by-step processes typically involved in the conventional SC administration using syringes. We then consider how OBIs may help alleviate these challenges in subsequent sections. **Figure 3** illustrates the general SC preparation and administration pathway, highlighting the key actions undertaken by pharmacy and nursing staff. The role of clinicians, primarily focused on diagnosis and prescribing, has been excluded for clarity.

Figure 3 Preparation and administration pathway for subcutaneous syringes, adapted from (Desai et al., 2025a; b)



Note: The listed actions corresponding to each process step are non-exhaustive and intended to summarise standard practice

Once a clinician prescribes treatment and a pharmacist reviews the prescription, pharmacy staff begin to gather the necessary materials for SC preparation, including the SC vial, syringe, transfer needle, and injection needle. A critical yet time-consuming step at this stage is warming the vial contents to room temperature, a requirement for many biologics. Depending on the product, this warming step on average can take approximately 30 minutes and, in some cases, longer, before the drug can be prepared (Biologic Meds, 2025). The main preparation process involves transferring the vial contents into a syringe under aseptic conditions using a transfer needle. The dose must then be manually set and primed, with care taken to avoid issues such as clogging. Once prepared, the syringe is transported to the clinical area, with strict attention paid to timing and temperature control due to the limited stability of reconstituted biologics, which often must be used within hours.

For the administration phase, nurses must exert substantial physical force using appropriate injection technique and maintain close oversight to ensure the medication is delivered safely and accurately. This entire multi-step process is time- and labour-intensive for both pharmacy and nursing teams. OBIs offer a valuable tool that could simplify or eliminate several of these burdensome steps, improving workflow efficiency and reducing the resource intensity of SC biologic administration.

5.2 Reducing care and workforce burden in clinical settings

Workforce shortages, particularly among nursing staff, have become especially acute in oncology care (Challinor et al., 2020). Nurses fulfil critical, patient-facing role in administering cancer treatments while managing extensive clinical and non-clinical responsibilities. However, more than one-third of nurses involved in MM care in Europe report insufficient specialised training (Murray et al., 2018), creating a concerning gap as modern cancer therapies are increasingly complex and require enhanced skill sets (Challinor et al., 2020).

The technical nature of syringe-based SC administration, spanning pharmacy preparation to nurse-delivered injection, requires targeted training for both professional groups. In this context, OBIs offer a potential solution to relieve training and operational pressures. Rather than acting as a substitute for workforce competence, OBIs can serve as an effective bridge that simplifies complex tasks and streamlines workflows.

5.2.1 Advantages in pharmacy and nursing workflow

OBIs directly address pharmacy preparation challenges through streamlined processes. A recent HCP preference study found that pharmacists across university-affiliated hospitals, non-academic centres, and private practices rated OBI preparation as simple and easy to learn, often involving only the insertion of a vial into the transfer base (Desai et al., 2025a). This streamlined approach eliminates many complex compounding steps required for traditional syringe preparation, leading to consistent pharmacist preference for OBI systems.

For nursing staff, OBIs combine the convenience of prefilled autoinjectors with the volume capacity of syringe pumps, requiring minimal pre-administration preparation (Desai et al., 2025b). In a randomised crossover study, both nurses and clinicians expressed strong preference for OBIs over syringe injections after direct experience with both delivery methods (Metz et al., 2021). The reduced physical force requirements are particularly significant, as sustained manual injection of high-volume biologics can cause repetitive strain injuries, a process that can last several minutes and place considerable physical demands on nursing staff (Desai et al., 2025b).

5.2.2 Reducing occupational hazards: chemical exposure, repetitive strain, and needlestick injuries

Even trained professionals face considerable occupational health risks during SC syringe preparation and delivery. Given that chemotherapy and other hazardous drugs are prepared in the same production units, HCPs handling biologics for SC administration remain at risk of exposure to harmful agents through inhalation, skin contact, or accidental splashes. Pharmacists, pharmacy technicians, and nurses are particularly vulnerable, although these risks also extend to staff involved in cleaning, transportation, and waste disposal (Graeve et al., 2017). Such exposures have been associated with adverse health effects, including skin disorders and reproductive complications (Fransman et al., 2007; Valanis et al., 1993). OBIs can mitigate these risks by enabling drug administration directly from sealed, original vials, thereby reducing the need for manual handling, vial transfer, and compounding under open conditions. This closed-system design lowers the likelihood of spillage or aerosolisation during preparation and administration, significantly reducing the risk of occupational exposure to hazardous substances.

In addition to chemical hazards, the compounding and preparation of sterile preparations require repetitive, forceful motions that may lead to musculoskeletal disorders and elevate needlestick injury risk (Desai et al., 2025a). With rising demand in service provision, both pharmacy and nursing staff face growing rates of hand-related repetitive strain injuries.

A meta-analysis of 42 studies involving over 36,000 nurses found an annual prevalence of work-related repetitive strain injuries exceeding 70% (Gorce and Jacquier-Bret, 2025), many stemming from injection-related activities. The financial impact is substantial, with direct and indirect costs including diagnostics, treatment, and lost productivity, reaching $50,000 to $100,000 per nurse with chronic injury (2007 estimates, unadjusted for inflation) (Gershon et al., 2007).

Needlestick injuries represent another major occupational concern, with prevalence rates among nurses ranging from 1.4% to as high as 80% across healthcare settings, largely reflecting underreporting in systems that rely on passive and voluntary surveillance (Lee et al., 2005). Underreporting is widespread, with fewer than half of injuries formally documented (Rezaei et al., 2017). Individual cases can cost between $51 and $5,000, depending on post-exposure management needs (Lee et al., 2005). OBIs specifically address these challenges by eliminating the sustained physical force requirements of manual injection, thereby reducing strain and injury risk for nursing staff.

Beyond addressing occupational safety and physical burden, OBIs reduce patient-related workload challenges. High-volume SC injections often require larger-gauge needles, which can increase patient anxiety and lead to missed or delayed appointments. In such cases, nurses must spend additional time counselling patients, adding to their clinical workload, and reducing overall care efficiency (Desai et al., 2025b).

OBIs address this challenge through their hidden needle design, reducing patient anxiety and the associated need for additional counselling time. The hands-free administration capability also allows patients to move freely during treatment, reducing nursing supervision requirements and enabling staff to attend to other patient care needs. These features provide a cumulative positive impact on care delivery by addressing multiple workforce challenges simultaneously. They establish a foundation for improving care delivery and capacity, optimising care efficiency and resource utilisation, and enabling the potential decentralisation of care delivery models.

Box 2 summarises the unmet needs associated with the SOC and how OBIs provide targeted solutions at the HCP level.

Summary Box 2 Mapping how on-body injectors address unmet needs at the HCP level.

CHALLENGES AND UNMET NEEDS OF STANDARD SC SYRINGES	HOW OBIS CAN ADDRESS CHALLENGES	REFERENCE
Time- and labour-intensive preparation and administration processes	Simplify preparation by requiring only vial insertion into the device, eliminating compounding steps and improving workflow efficiency	(Desai et al., 2025b; a)
Insufficient training provided for oncology staff despite technical requirements of syringe preparation and administration	Reduce training burden through ease of use, supporting quicker onboarding of staff	(Challinor et al., 2020; Desai et al., 2025b; a; Murray et al., 2018)
Risk of exposure to hazardous agents during drug preparation and handling	Utilise closed-system designs that minimise manual handling, vial transfer, and open compounding, reducing hazardous exposure risk	(Graeve et al., 2017)
Work-related strain injuries from repetitive manual injections	Remove the need for sustained manual force during injection	(Desai et al., 2025b; Gorce and Jacquier-Bret, 2025; Lee et al., 2005)
Needlestick injuries during preparation and administration	Eliminate the need for needle transfer and manual injection and incorporate needle safety mechanisms	(Desai et al., 2025b; a; Guo et al., 2024)

5.3 Improving health care workflow flexibility and service delivery

5.3.1 Enhancing care efficiency and expanding operation capacity

The preparation of SC injections faces a fundamental bottleneck in healthcare settings. Refrigerated biologics must be warmed to room temperature before administration (see Section 5.1). This process on average requires around 30 minutes and can create operational burden for pharmacy staff (Biologic Meds, 2025). Beyond the direct time cost, these warming requirements introduce uncertainty and delay into pharmacy workflows, reduce overall efficiency, and limit patient throughput capacity. The cumulative impact of warming delays becomes significant even with conservative estimates. For instance, a 15-minute warming period for just 40 patients per month results in 10 hours of accumulated waiting time, during which staff cannot proceed with drug preparation or administration. A time-and-motion study of SC injection preparation revealed that up to half of the total preparation time may be spent simply waiting for drugs to reach room temperature (Slavcev et al., 2021).

These delays generate negative spillover effects throughout the care pathway, including increased risk of drug wastage. Reconstituted biologics are temperature-sensitive with limited stability once prepared, requiring administration within a narrow time window. When patients fail to attend appointments after preparation has begun, the combination of warming requirements and shelf-life constraints can result in unusable, discarded medication. Such wastage is costly in oncology, where biologics are frequently high-cost and paired with on-patent regimens (Hess et al., 2018; Rajangom et al., 2025).

OBIs offer an effective solution to these inefficiencies. A study investigating biologic delivery via an OBI found that the device's internal drug transfer mechanism, combined with the patient's body heat, can effectively warm the drug in situ, reducing or potentially eliminating warming time requirements (Gunnerson et al., 2024). This feature enables (near-)immediate preparation without delay and helps mitigate drug wastage linked to

patient no-shows. However, it is important to note that this feature is not universal across all OBI platforms.

The operational advantage of OBIs is well-reflected in HCP preference studies. In a pharmacist-focused survey comparing OBIs to SC syringes, time savings, particularly through the elimination of warming steps, was the most frequently cited reason for preferring OBIs (Desai et al., 2025a). When pharmacists were informed that the device could eliminate warming time, 100% preferred OBIs over syringes, compared to 87% in scenarios where warming time benefits were not specified.

Beyond time savings, OBIs also support improved dose accuracy and reduced product wastage. Traditional vial-based SC delivery often results in unnecessary product loss due to overfill and holdup volume i.e., residual drug left in syringes or vials after preparation (Warne and Mahler, 2018). OBIs are designed to minimise holdup volume and deliver precise, programmable doses directly from original vials, supporting more efficient use of expensive therapies.

OBIs also provide greater flexibility in preparation location. Unlike traditional syringe-based injections, which typically require compounding in sterile pharmacy environments, some OBIs can be prepared and activated chairside by trained nurses (Desai et al., 2025b). This capability alleviates pressure on pharmacy departments, which are increasingly strained by staffing shortages and rising compounding demands, while improving clinic efficiency by bringing drug preparation closer to the point of care.

This decentralisation is particularly valuable given the well-documented risks and operational complexities of sterile compounding. Errors such as incorrect dosing, contamination, improper labelling, or inappropriate needle sizing can lead to treatment delays, near-miss events, or direct patient harm (Zhou et al., 2014). These mistakes carry significant clinical and financial implications, especially in oncology where treatments are high-cost, time-sensitive, and often part of tightly sequenced regimens.

By simplifying preparation and administration pathways, OBIs reduce procedural variability and ease HCP workload through consistent, controlled delivery. Many OBI platforms allow direct use of original drug vials with automated filling capabilities, enabling HCPs to multitask or attend to other responsibilities during preparation. Collectively, these features support greater workflow flexibility, expand care delivery capacity, and promote more efficient utilisation of both human and material resources.

5.3.2 Supporting workforce sustainability and enabling care decentralisation

The benefits of OBIs at the individual patient and HCP levels aggregate to generate broader health system value. By simplifying drug preparation and administration process, reducing manual handling requirements, and lowering occupational hazard risks, OBIs help alleviate the cumulative physical and psychological burden placed on frontline healthcare staff. These efficiencies support workforce sustainability, an increasingly critical concern amidst ongoing staff shortages, rising treatment complexity, and growing healthcare demands (Dixon-Woods et al., 2024).

Nurse burnout carries well-documented implications for health system functioning, including increased absenteeism, staff turnover, medication errors, and overall reductions in care quality (Teng et al., 2010). Although all HCPs face burnout risks, rates are particularly elevated among nurses, especially those working in oncology. Across clinical settings, nursing staff consistently reported that transitioning to OBIs reduced their workload, freed up time, and alleviated stress (Desai et al., 2025b), potentially improving job satisfaction and retention rates.

Payer and provider preferences align with these workforce-related benefits. In semi-structured interviews, payers expressed a generally positive perception of novel OBI devices, citing advantages such as simplicity, ease of use, convenience, improved treatment adherence, compact design, and the potential to alleviate needle phobia (Desai, Kenney and Pezalla, 2024). From a scheduling perspective, over one-third of German clinicians prescribing a supportive cancer therapy reported selecting same-day administration using OBIs rather than SC syringes, primarily to avoid requiring return visits (Brett Hauber et al., 2018). Although clinician preference for OBIs is largely shaped by past experiences and practice patterns, these choices highlight recognition of OBIs' potential to ease capacity constraints and support more efficient use of infusion centre resources.

Preferences for administration flexibility and reduced in-clinic demands reflect a broader policy shift towards decentralised care delivery. National health strategies such as the UK's 10-Year Cancer Plan and France's Haute Autorité de Santé's 2025-2030 Strategic Project, and Spain's Global Health Strategy 2025-2030 exemplify this trend (HAS, 2025; Ministerio de Sanidad, 2025; UK Gov, 2025), emphasising more efficient, patient-centred care delivery models.

While OBI use for home administration typically depends on associated medication licensing, payers acknowledged their potential to support future transitions toward community-based and, where appropriate, home-based care (Desai, Kenney and Pezalla, 2024). As healthcare systems increasingly prioritise capacity optimisation and resource efficiency, the value proposition of OBIs is likely to strengthen substantially.

Box 3 summarises the unmet needs associated with the SOC and how OBIs provide targeted solutions at the health system level.

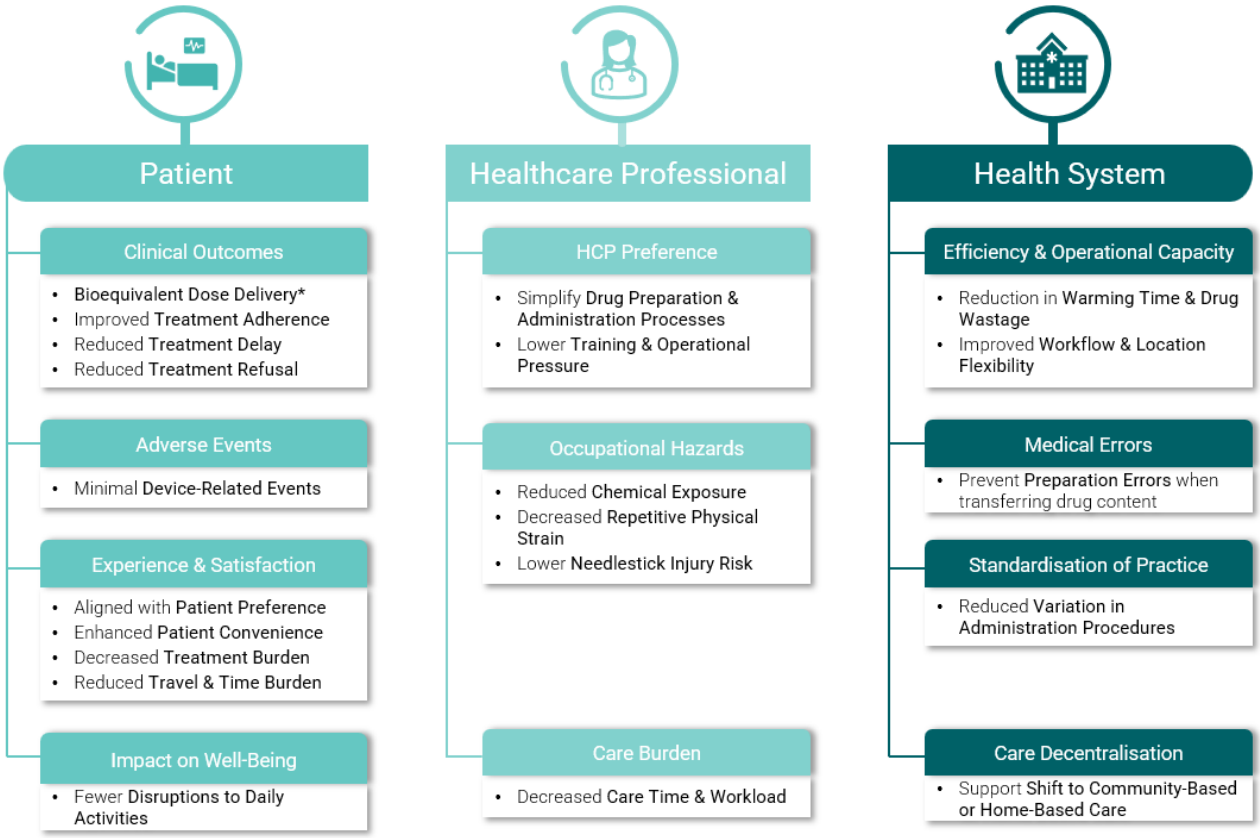
Summary Box 3 Mapping how on-body injectors address unmet needs at the health system level.

CHALLENGES AND UNMET NEEDS OF STANDARD SC SYRINGES	HOW OBIS CAN ADDRESS CHALLENGES	REFERENCE
Biologics warming requirements introduce uncertainty and delays in pharmacy workflows. This can contribute to negative spillover effects, including increased drug wastage, as reconstituted biologics have limited stability once prepared	Internal drug transfer and on-body warming from patient body heat can reduce or eliminate pre-administration warming time, enabling near-immediate preparation and reducing drug wastage from patient no-shows[1]	(Desai et al., 2025a; Gunnerson et al., 2024)
Product loss due to residual drug volume in traditional vial-based SC delivery	Allow direct drug administration from original vials	(Warne and Mahler, 2018)
Reliance on compounding in sterile pharmacy environments, adding pressure to already strained pharmacy capacity	Enable chairside preparation and activation by trained nurses, alleviating pharmacy workload and improving clinic efficiency	(Desai et al., 2025a)
Existing physical and emotional burden on HCPs, contributing to stress and reduced efficiency	Reduce HCP workload and stress by simplifying preparation and aligning with HCP preferences (clinicians, nurses, and pharmacy staff)	(Desai et al., 2025b; Teng et al., 2010)
Centralised care delivery limits flexibility and patient access	Support decentralised care models by enabling administration in community-based or home settings	(HAS, 2025; Ministerio de Sanidad, 2025; UK Gov, 2025),

[1] Note that drug warming mechanisms may be present in certain OBIs but are not universal across all platforms.

Building on the analytical framework outlining unmet needs associated with existing drug administration (**Figure 2**) and the explored impacts of OBIs, we summarise the identified potential benefits of OBIs across patients, HCPs, and health systems, based on the literature, in **Figure 4**. These are compared with SC syringe injections, which represent the current SOC.

Figure 4 The potential benefits associated with on-body injectors (OBI) in cancer care, compared to standard subcutaneous manual syringe injections.



*The bioequivalent dose delivery of OBIs is compared to manual subcutaneous syringe injections.

6 Future directions for administration innovation

This research identifies that OBIs, as innovative administration devices, can unlock the full value of SC delivery in oncology. However, despite their clinical and potential benefits, the adoption of OBIs and similar devices is hindered by structural barriers and misaligned incentives across healthcare systems.

6.1 Barriers to adoption of novel delivery devices in cancer care

One major barrier is the additional costs of the device component, which often leads to restrictive reimbursement criteria and limited funding pathways (Tanenbaum and Commissariat, 2022). These constraints influence clinician prescribing behaviour and reduce uptake. This challenge is compounded by healthcare budget silos where device costs may be borne by a specific provider sector (e.g., oncology departments), while the broader health system benefits including reduced workload, improved adherence, and fewer hospital visits, are neither adequately captured nor rewarded. In fact, payer do not always view OBI as an integrated component of the medicine and may therefore fail to account for the full value of a drug-device combination (Desai, Kenney and Pezalla, 2024). This includes overlooking healthcare costs and cost savings beyond the medicine and device price when comparing the product with other SC delivery methods. This limited perspective fails to account for the comprehensive value proposition that OBIs offer across the care continuum.

These cost concerns further complicate reimbursement and adoption. Clinical uptake of device components may lag behind their paired medicine because devices typically require distinct reimbursement and coding pathways (CMS, 2024). Healthcare providers may hesitate to prescribe newly launched devices that lack specific billing or procedure codes, delaying patient access even when the drug is already approved and reimbursed. The time required to establish these codes can extend reimbursement timelines and time to adoption. Beyond these procedural delays, drug-device combinations face regulatory and health technology assessment (HTA) requirements, including data on component compatibility and human factors such as user experience (FDA, 2024; Schneider, 2023), alongside standard clinical and economic evidence, adding further time and uncertainty prior to launch.

A related challenge lies in the value assessment of drug-device combinations. Depending on the marketing authorisation and whether the OBI is supplied exclusively with the drug or separately, such combinations may or may not be classified as single integral products (EMA, 2019). In both cases, similarly to combination therapies, demonstrating the added value of OBIs within traditional cost-effectiveness frameworks is difficult and not explicitly delineated by most HTA agencies (Briggs et al., 2025; NICE, 2023). This creates challenges for reimbursement and pricing, particularly when the paired medicine is already priced near the payer's willingness-to-pay threshold, leaving limited economic headroom for add-on technology such as administration devices (Briggs et al., 2025). This is a challenge that is more likely to arise in countries using cost-effectiveness analyses (and more specifically the QALY metric) in reimbursement decisions, such as the UK. Unlike combination medicines that may offer additive or synergistic therapeutic effects, delivery devices are often viewed as ancillary components and less impactful on clinical outcomes such as cancer progression or survival, making them more vulnerable to undervaluation.

Yet, OBIs are specifically engineered for compatibility with particular formulations and designed to enhance both patient and HCP experiences. The non-clinical benefits they

provide such as improved treatment experience, ease of use, and reduced occupational risk, are inadequately reflected in current evaluation frameworks. Without accounting for patient and HCP preferences, the full value of these technologies remains under-recognised.

6.2 Capturing the full value of administration devices

The challenges of valuing novel administration technologies are not unique to OBIs. Traditional HTA frameworks tend to focus heavily on survival and disease progression endpoints, often overlooking non-health benefits that matter significantly to patients, HCPs, and health systems (Mundy et al., 2024; Syeed et al., 2022).

As highlighted throughout this report, compared with conventional SC syringe administration, OBIs accommodate high-volume formulations, enable automated, hands-free delivery, and incorporate features that improve patient comfort and safety. These include smaller, shorter, and concealed needles, as well as retractable safety mechanisms. Such design elements can significantly enhance patient experience, reduce needle-related anxiety, improve treatment adherence, and minimise disruptions to daily activities. For HCPs, OBIs simplify both preparation and administration processes, reduce care burden and time requirements, and lower the risk of physical strain and occupational injuries. In turn, these benefits might contribute to improved job satisfaction, reduced absenteeism, and greater clinic efficiency.

At the health system level, OBIs offer potential to streamline workflows, expand treatment capacity, and enable care decentralisation, particularly important in resource-constrained settings. These capacity-enhancing efficiencies contribute to healthcare sustainability and may improve cost-effectiveness. However, they are rarely captured in traditional economic evaluations, which tend to prioritise direct clinical outcomes.

A recent German position paper (Piontek and Stockert, 2023) highlights the urgent need for capacity-enhancing innovations to address hospital workforce and infrastructure shortages. Promoting their adoption will require changes at multiple levels—including more comprehensive definitions of value, recognition of pathway-wide effects, and explicit consideration of opportunity costs.

To address this evaluation gap, value assessment frameworks must evolve to incorporate broader dimensions of value—such as staff workload, caregiver impact, organisational efficiency, and patient preferences. Without this shift, high-impact technologies risk being systematically undervalued, particularly in oncology, where the use of innovative delivery devices remains limited (Guo et al., 2024). This points to a promising line of research focused on better integrating capacity-enhancing technologies into HTA and policy decision-making.

6.3 Policy outlook: advancing anti-cancer therapy delivery

Despite current undervaluation of novel administration technologies, emerging trends suggest growing recognition of their importance. Regulatory approvals of biologic-device combination products are increasing (Guo et al., 2024), and new studies are beginning to evaluate not only therapeutic efficacy but also the delivery and operational aspects of cancer treatment. This reflects a paradigm shift towards understanding how treatment experience, convenience, and workflow optimisation impact real-world outcomes and health system performance.

Research into SC formulation has highlighted not just the pharmacological innovations in biologics but also the practical challenges of preparation, administration, and integration into clinical pathways. As more SC alternatives to IV administration enter the oncology pipeline, there is increasing urgency to consider delivery innovations as integral components of holistic cancer care—encompassing workflow optimisation, capacity management, and HCP resource use.

Decision-makers including payers and healthcare providers share responsibility for ensuring that value assessments of administration technologies are comprehensive and that innovations receive adequate recognition and reimbursement. HTA bodies can support this shift by expanding value frameworks to incorporate impact on care capacity, patient-centric outcomes, and operational considerations. Such efforts will help create a more supportive reimbursement and policy environment that promotes investment in high-value delivery technologies, while recognising the preferences of patients, carers, and HCPs in cancer treatment design and implementation.

While SC formulations currently represent a smaller share of oncology medicines compared to IV counterparts, this is expected to change. As the portfolio of SC biologics expands, the role of novel administration technologies will grow in parallel, extending their benefits across a broader range of cancer types and care settings. Leveraging these delivery innovations strategically can shape more efficient and sustainable cancer care systems for the future.

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7 Appendices

7.1 Appendix A. Search strategy

Searches were conducted in Embase, Ovid MEDLINE, and Ovid Nursing Database.

The search strategy followed a two-part approach. Search one addressed research question 1, aiming to identify the current standard-of-care and treatment pathways for multiple myeloma (MM) and the associated challenges, across the geographical scope. Search two addressed research questions 2 and 3, aiming to capture the impacts of adopting on-body injectors (OBI) in cancer care.

The strategy was developed using the PICO (Population, Intervention, Comparator, Outcome) framework. The Intervention component related to OBIs was separated from the main PICO construction, as its inclusion would have excluded many relevant articles not explicitly using OBI-related terms but still addressing the other components.

Two distinct sets of exclusion criteria were applied. For the first search identifying the current MM drug delivery landscape, we excluded articles that were not peer-reviewed, unrelated to MM, outside the geographical scope, or did not focus on SOC or associated unmet needs. For the second search exploring how OBIs can address identified challenges, we excluded articles that were not peer-reviewed, unrelated to cancer, focused solely on clinical efficacy assessments, irrelevant to device technology, or only explored cost- and funding-related aspects of the device.

Search one:

(multiple myeloma OR Kahler* disease OR myelomatosis OR monoclonal gammopathy OR ((plasma cell) adj2 (myeloma OR dyscrasia* OR malignan*))) AND

((administ*) adj2 (drug* OR treatm* OR infusion) OR (resource adj1 (us* OR utili$ation)) OR ((care OR treatment OR clinical) adj2 (pathway OR guideline OR pattern)) OR patient journey OR standard adj2 care OR current practice) AND

(challeng* or limitation* or barrier* or gap*) AND

(adherence OR time OR (care adj2 time) OR efficien* OR communicat* OR (wait* adj2 time?) OR needs OR workload OR wastage OR constitution* OR risk* OR nurs* OR hospital) OR (needle* OR syringe* OR injection* OR intravenous OR *cutaneous) adj3 (anxious OR anxiety OR fear* OR reject*) AND

(United Kingdom OR UK OR England OR Scotland OR Wales OR France OR Germany OR Italy OR Spain OR Europe*)

Search two:
(on-body inject* OR on-body delivery system)

Table 2 Illustration of searches

PICO	#	Search strategy	N
P Disease	1	(multiple myeloma OR Kahler* disease OR myelomatosis OR monoclonal gammopathy OR ((plasma cell) adj2 (myeloma OR dyscrasia* OR malignan*)))	206,210
I Device-specific	2	(automated drug administration device* OR automated infusion* OR smart infusion pump* OR drug delivery device*)	9,004
	3	(on-body inject* OR on-body delivery system) [Search two]	184
C Current practice	4	(administ*) adj2 (drug* OR treatm* OR infusion) OR (resource adj1 (us* OR utili$ation)) OR ((care OR treatment OR clinical) adj2 (pathway OR guideline OR pattern)) OR patient journey OR standard adj2 care OR current practice	332,409
	5	challeng* or limitation* or barrier* or gap*	6,308,148
O Benefits of the device	6	adherence OR time OR (care adj2 time) OR efficien* OR communicat* OR (wait* adj2 time?) OR needs OR workload OR wastage OR constitution* OR risk* OR nurs* or hospital	38,855,962
	7	(needle* OR syringe* OR injection* OR intravenous OR *cutaneous) adj3 (anxious OR anxiety OR fear* OR reject*)	10,035
Region	8	United Kingdom OR UK OR England OR Scotland OR Wales OR France OR Germany OR Italy OR Spain OR Europe*	36,521,798
	9	6 OR 7	38,859,361
	10	1 AND 4 AND 5 AND (6 OR 7) AND 8 [Search one]	218
Filters		(limit to English language) (limit to humans) (limit to yr="2015 - Current")	

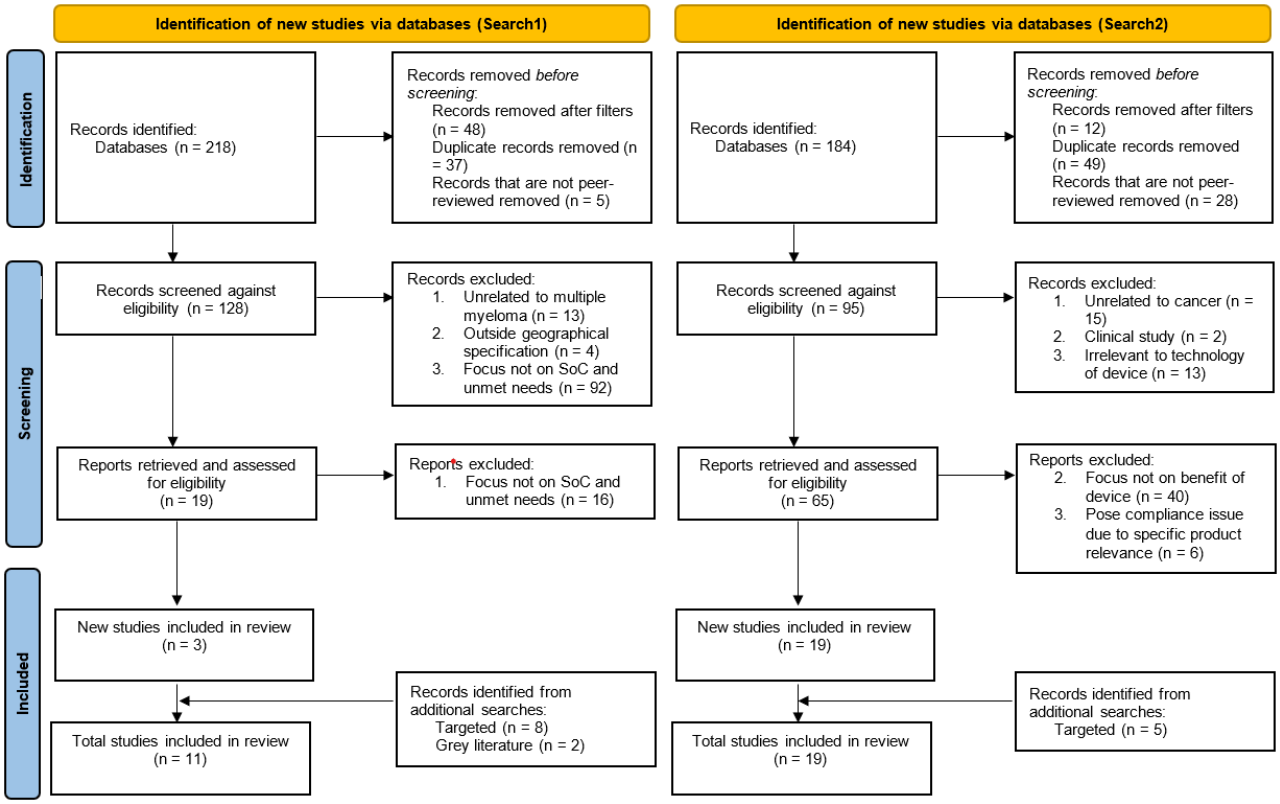
7.2 Appendix B. Grey literature

To supplement the information retrieved from peer-reviewed publications (Appendix A), we also did a targeted review of grey literature exploring the following sources:

1. The Clinical Journal of Oncology Nurses
2. The International Myeloma Foundation Nurse Leadership Board
3. Multiple Myeloma Europe guidance
4. European Society for Medical Oncology (ESMO) guidance
5. National Institute for Health and Care Excellence (NICE) guidance

7.3 Appendix C. Study identification, screening, and inclusion

Figure 5 PRISMA flow diagram illustrating study inclusion.



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